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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,306	02/12/2002	Jan Urban Kristoffer Hellstrand	MAXIM.026C3	1217

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EXAMINER	
HOLLERAN, ANNE L	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/076,306	HELLSTRAND ET AL.	
	Examiner	Art Unit	
	Anne Holleran	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-16 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 116 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-16 are pending and examined on the merits.

Priority

2. Applicant is advised to update the status of the priority application 09/516,641. Since the application has become a patent, the expression "now U.S. Patent No. 6,375,946" should follow the filing date of the application.

Information Disclosure Statement

3. Some of the references cited in the PTO-1449 were not found with the parent applications and could not be considered. Therefore, the citations were not initialed. Applicant is invited to send courtesy copies of the missing references.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2 and 11 of U.S. Patent No. 6,071,501. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 2 and 11 are specifically drawn to methods of administering compounds that are NK cell activating cytokines or NK cell activating flavanoids, where the compounds are administered in combination with a histamine, other H_2-receptor agonists or serotonin, and where the administration is in vivo. While in vivo administration is broader in scope than a methods comprising administering to subjects suffering from neoplastic disease, the specification of U.S. Patent No. 6.071,501 teaches one example of the use of the claimed methods in U.S. patent 6,071,501, where the use is the inhibition of tumor growth (see column 5, lines 2-5).

6. Claims 1-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2 and 11 of U.S. Patent No. 6,375,946. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 2 and 11 are specifically drawn to methods of administering compounds that are NK cell activating cytokines or NK cell activating flavanoids, where the compounds are administered in combination with a histamine, other H_2-receptor agonists or serotonin, and where the administration is in vivo. While in vivo administration is broader in scope than a methods comprising administering to subjects suffering from neoplastic disease, the specification of U.S. Patent No. 6,375,946 teaches one example of the use of the claimed methods in U.S. patent 6,375,946, where the use is the inhibition of tumor growth (see column 5, lines 2-5).

7. Claims 1-8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,063,373. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-5 are specifically drawn to methods for treating neoplastic disease comprising administering compounds that are NK cell activating cytokines or NK cell activating flavanoids, where the compounds are administered in combination with a histamine, other H_2-receptor agonists or serotonin. While the claims of 6,063,373 do not recite explicitly that the compounds are administered to a subject that has been identified as a subject suffering from a neoplastic disease, the claims of 6,063,373 recite that the compounds are administered to a patient receiving radiation therapy or chemotherapy. Implicit in treating this patient population is a step of first identifying these patients as suffering from neoplastic disease, because a patient receiving radiation therapy or chemotherapy is a patient that has been identified as a subject suffering from neoplastic disease.

8. Claims 1-8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,245,563. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-5 are specifically drawn to methods for treating neoplastic disease comprising administering compounds that are NK cell activating cytokines or NK cell activating flavanoids, where the compounds are administered in combination with a histamine, other H_2-receptor agonists or serotonin. While the claims of 6,245,563 do not recite explicitly that the compounds are administered to a subject that has been identified as a subject suffering from a neoplastic

disease, the claims of 6,245,563 recite that the compounds are administered to a patient receiving radiation therapy or chemotherapy. Implicit in treating this patient population is a step of first identifying these patients as suffering from neoplastic disease, because a patient receiving radiation therapy or chemotherapy is a patient that has been identified as a subject suffering from neoplastic disease.

Claim Rejections - 35 USC § 112

9. Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 8 are indefinite because of the phrase "effective amount". Independent claims 1 and 8 contain the step of administering to a subject suffering from a neoplastic disease "an effective amount" of an NK cell activating cytokine or an NK cell activating flavanoid, but the claims fail to recite what the amount is effective for. For example, is the amount effective for activating NK cells in vitro or is it effective for inhibiting tumor growth.

10. Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis for this rejection is that the specification fails to describe the active step of administering to a subject suffering from neoplastic disease an effective amount of an NK cell

activating cytokine or an NK cell activating flavonoid, because the specification lacks a description of "effective amounts".

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is for purposes of the 'written description' inquiry, "*whatever is now claimed" (*see page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now claimed." (See Vas-Cath at page 1116.)

The claims are drawn to methods for inhibiting tumor growth in a subject suffering from neoplastic disease, comprising administering to the subject an effective amount of an NK cell activating cytokine or an NK cell activating flavonoid, and also administering either a compound effective to inhibit the production or release of hydrogen peroxide (histamine, other H_2 receptor agonists or serotonin), or an effective amount of a compound that is a hydrogen peroxide scavenger. The specification contemplates using methods for activating NK cells for the purpose of inhibiting tumor growth, but fails to provide any working examples or any contemplation of appropriate dosages of the compounds to be administered. The specification refers to broad ranges of dosages that are contemplated to be effective for activating NK cells, but does not teach these dosages as effective for inhibiting tumor cell growth.

The skilled artisan cannot envision the appropriate dosages because the specification provides no guidance for dosages effective in a method that has the purpose of inhibiting tumor growth and also because the claims do not clearly set forth what the amounts to be administered are effective for. Because the skilled artisan cannot readily envision the appropriate dosages to

be used in methods for the purpose of inhibiting tumor growth, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of manufacturing or testing the claimed process. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for making or testing it. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. 112, is severable from its enablement provision. (See page 1115).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 571-1600.

Anne L. Holleran
Patent Examiner
October 1, 2004

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
10/1/04